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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,812	05/08/2007	Hiroshi Kanai	NIHE-40596	1931

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EXAMINER	
PENG, BO JOSEPH	
ART UNIT	PAPER NUMBER
3768	

NOTIFICATION DATE	DELIVERY MODE
11/14/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/581,812	KANAI ET AL.	
	Examiner	Art Unit	
	BO J. PENG	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,5 and 6* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,5 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *02 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This action is responsive to the Amendments/Arguments filed on 11/05/2010. Claims 1, 2, 5, and 6 have been amended. Claims 3, 4 and 7-12 have been canceled. Claims 1, 2, 5, and 6 are pending.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/27/2010 has been entered.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 2, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro et al. (US 5830131), in view of Hasegawa et al. (Evaluation of Regional Elastic modulus of Cylindrical Shell with Nonuniform Wall thickness) and further in view of Selzer et al. (Improved common carotid elasticity and intima-media thickness measurements from computer analysis of sequential ultrasound frames, 2001, Atherosclerosis, 154, 185-193, hereinafter Selzer '2001) and Iinuma et al. (Pat. No. 5,785,654, hereinafter Iinuma '654).

In re claims 1, 2, 5, and 6, Caro discloses an ultrasonic diagnostic method and apparatus for diagnosing vascular endothelial function by using an ultrasonic diagnostic apparatus (see col. 3 lines 14-40), comprising a transmitter/receiver for transmitting and receiving ultrasonic waves (see col. 22 lines 22-45), a phase detector for detecting a phase of the received ultrasonic echo (see fig. 5, col. 22 lines 22-45, and col. 23 lines 18-40; a phase is necessarily detected), and an arithmetic unit for calculating elastic modulus of vascular wall based on an ultrasonic echo obtained through phase detection (see col. 23 lines 18-40, the modulus is calculated based an echo that includes a phase), wherein said method comprising: a step (A) of transmitting ultrasonic waves into tissues of living body including vascular wall, and receiving an ultrasonic echo obtained when said ultrasonic waves is reflected and scattered by said vascular wall, said

vascular wall having a thickness (see col. 22 lines 22-45); a step (B) of detecting a phase of said ultrasonic echo (see col. 22 lines 22-45; a phase is necessarily detected); and of determining elastic modulus of said vascular wall from a thickness change and a blood pressure value (see col. 23 lines 18-40; the tunica intima and tunica media are included in the vascular wall). Caro discloses that the elastic modulus of said vascular wall comes from the thickness of the wall (see col. 23 lines 20-40). Caro discloses a piezoelectric sensor that senses arterial wall displacement and position (see col. 7 lines 9-17), discloses that the phase of the waveform corresponds to the blood pressure for many frequencies and is predictable based on between the velocity of an exciter wave and blood pressure (see col. 10 lines 42-62), and that the thickness of a vessel, modulus, or the vessel radius can change over time. Caro discloses that the thickness of a vessel, modulus, or the vessel radius can change over time including when blood is flowing through it and there is need to optimize treatments based on these parameters (see col. 23 lines 18-40).

Caro fails to teach calculating elastic modulus of specific region such as tunica intima and tunica media excluding tunica adventia, though Caro teaches calculating elastic modulus the entire vascular wall that includes tunica intima and media.

Hasegawa discloses that a vessel changes thickness in a pulsatile fashion. To measure this thickness, a vibration velocity is measured first by measuring the phase shift between the ultrasonic pulses. Then the vibration velocity is measured for the inner and outer surface uses this to find the change in thickness as a function of time over a period of time. Hasegawa discloses that if plaque is in the vessel, then the

vessel is not a perfect cylinder, so more calculation is needed. The vessel thickness is divided into layers and the modulus is calculated corresponding to each layer thickness. Thus the modulus can be defined for every thickness change in the blood vessel for any portion in the vessel's perimeter (see English translation of document p. 1-6 of attached NPL).

Therefore, it would have been obvious to one of ordinary skill in the art to include elastic modulus calculations from each individual layer of a vascular wall as taught by Hasegawa in the method of Caro in order to provide a more accurate characterization of a diseased vessel with a non-uniform diameter.

The combine teaching of Caro and Hasegawa however fails to explicitly disclose calculating an elastic modulus of a region including a tunica intima and tunica media of said vascular wall and excluding a tunica adventia of said vascular wall.

Selzer 2001 teaches improved initima-media thickness measurements from computer analysis of sequential ultrasound frames (whole article, and fig. 1), and also teaches storing and displaying changes over time. (fig. 1, page 188, 3.2, and discussion).

In addition, Iinuma '654 teaches on the M-mode image of FIG. 8, a start point is designated to each of tunica intima and tunica externa of the posterior wall of the left ventricle so as to obtain each path. Then, the change in a time series of the distance between two paths can be obtained as a change in a time series of the thickness of the cardiac muscle. Moreover, from the change in a time series of the thickness of the cardiac muscle, there can be measured functional data such as the contraction velocity

of the cardiac muscle, the maximum and minimum values of the thickness of the cardiac muscle, a contraction ratio, etc. FIGS. 13 and 14 show a change 37 in a time series of the thickness of the cardiac muscle, and a change 39 in a time series of the contraction velocity, i.e., a graph in which change 37 is time-integrated. Moreover, as shown in FIG. 15, there can be obtained a velocity change of each of tunica intima and tunica externa, and a change in a time series of the velocity difference (velocity change of thickness of cardiac muscle) between tunica intima and tunica externa. Hence, the elastic property of tunica externa (tunica adventia) can be measured and obtained, and be display and stored (col. 4, lines 10-31, col. 8, line 60 - col. 9, line 44).

Because Selzer '2001 teaches calculating an elastic modulus of tunica intima and tunica media, and Iinuma '654 teaches calculating an elastic modulus of tunica intima and tunica externa (tunica adventia), one of an ordinary skill in the art would decide whether to include or exclude the elastic modulus of tunica externa (tunica adventia).

Therefore, It would have been *prima facie* obvious to one of ordinary skills in the art at the time of invention to modify the method and device of Caro to include the multilayer thickness and elastic modulus calculations of Hasegawa, to include the elastic modulus calculation of tunica intima and tunica media of Selzer '2001, and include the teaching of measurements of tunica externa (tunica adventia) of Iinuma '654 in order to make optimal calculations of thickness changes and blood pressure while having a freedom for choosing whether to include or exclude the elastic modulus of tunica externa (tunica adventia).

Response to Arguments

5. Applicant's arguments with respect to claims 1, 2, 5, and 6 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BO J. PENG whose telephone number is (571)270-1792. The examiner can normally be reached on Monday thru Thursday: 8:30am-5:00pm, Alternate Fridays, EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BO J. PENG /
Examiner, Art Unit 3768

/LONG V. LE/
Supervisory Patent Examiner, Art Unit 3768